#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re /	Application of:	)	
Udo k	(RUPKA	)	
Applic	cation No.: 10/561,434	)	Group Art Unit:
Filed:	December 20, 2005	)	Examiner:
For:	NOVEL SURFACE PROTEIN (HBsAg) VARIANT OF THE HEPATITIS B VIRUS	)	

### U.S. National Phase of International PCT Application No. PCT/EP2004/006516

MAIL STOP PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§1.56 and 1.97(b), applicant brings to the Examiner's attention the documents listed on attached Form PTO/SB/08. Copies of the listed documents are attached. Applicants respectfully request that the Examiner consider the documents listed on attached Form PTO/SB/08 and indicate that they were considered by making an appropriate notation on this form.

This Supplemental Information Disclosure Statement is being filed within three months of the filing date of the above-referenced application.

Customer No. 22,852 Attorney Docket No. 05552.1464

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 3, 2006

By: Carol P. E. nour-Carol P. Einaudi Reg. No. 32,220

Enclosures CPE/FPD/gah

IDS	Form	DTO/SB/09	Substitute for form	1440A/DTC
IUO	FOITH	PIU/SB/UK	Substitute for form	1449A/P10

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	3

С	omplete if Known	-
Application Number	10/561,343	
Filing Date	December 20, 2005	
First Named Inventor	KRUPKA	
Art Unit		
Examiner Name		
Attomey Docket Number	05552.1464	<del>-</del>

	U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS						
Examiner Initials	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2</sup> (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		US-		**			

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

		FORE	IGN PATENT	DOCUMENTS		
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		WO-02/079217 A1	10-10-2002	ABBOTT LABORATORIES		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
		LEE; "HEPATITIS B VIRUS INFECTION"; The New England Journal of Medicine, Vol. 337, No. 24, pages 1733-1745, (1997)	
		TIOLLAIS et al.; "THE HEPATITIS B VIRUS"; Nature, Vol. 317, pages 489-495, (1985)	
		GERLICH et al.; "FUNCTIONS OF HEPATITIS B VIRUS PROTEINS AND VIRUS ASSEMBLY"; Viral Hepatitis and Liver Disease, pages 121-134, (1991)	
		BLUM; "VARIANTS OF HEPATITIS B, C AND D VIRUSES: MOLECULAR BIOLOGY AND CLINICAL SIGNIFICANCE"; Digestion, Vol. 56, pages 85-95, (1995)	
		OKAMOTO et al; "GENOMIC HETEROGENEITY OF HEPATITIS B VIRUS IN A 54-YEAR-OLD WOMAN WHO CONTRACTED THE INFECTION THROUGH MATERNO-FETAL TRANSMISSION"; Japan. J. Exp. Med., Vol. 57, No. 4, pages 231-236, (1987)	
		CARMAN et al.; "VIRAL GENETIC VARIATION: HEPATITIS B VIRUS AS A CLINICAL EXAMPLE"; The Lancet, Vol. 341, pages 349-353, (1993)	
		COUTROUCÉ et al.; "BIBLIOTHECA HAEMATOLOGICA No. 42"; pages 1-19, (1976)	
		NORDER et al.; "MOLECULAR BASIS OF HEPATITIS B VIRUS SEROTYPE VARIATIONS WITHIN THE FOUR MAJOR SUBTYPES"; Journal of General Virology, Vol. 73, pages 3141-3145, (1992)	
		NORDER et al.; "COMPLETE GENOMES, PHYLOGENETIC RELATEDNESS, AND STRUCTURAL PROTEINS OF SIX STRAINS OF THE HEPATITIS B VIRUS, FOUR OF WHICH REPRESENT TWO NEW GENOTYPES"; Virology, Vol. 198, pages 489-503, (1994)	
		COOREMAN et al.; "CHARACTERIZATION OF THE REACTIVITY PATTERN OF MURINE MONOCLONAL ANTIBODIES AGAINST WILD-TYPE HEPATITIS B SURFACE ANTIGEN TO G145R AND OTHER NATURALLY OCCURRING "a" LOOP ESCAPE MUTATIONS"; Hepatology, Vol. 30, No. 5, pages 1287-1292, (1999)	
		TERRAULT et al.; "INCIDENCE AND CLINICAL CONSEQUENCES OF SURFACE AND POLYMERASE GENE MUTATIONS IN LIVER TRANSPLANT RECIPIENTS ON HEPATITIS B IMMUNOGLOBULIN", Hepatology, Vol. 28, No. 2, pages 555-561, (1998)	
		TILLMAN et al.; "MUTATIONAL PATTERN OF HEPATITIS B VIRUS ON SEQUENTIAL THERAPY WITH FAMCICLOVIR AND LAMIVUDINE IN PATIENTS WITH HEPATITIS B VIRUS REINFECTION OCCURRING UNDER HBIg IMMUNOGLOBULIN AFTER LIVER TRANSPLANTATION"; Hepatology, Vol. 30, No. 1, pages 244-256, (1999)	
		HUNT et al.; "CLINICAL RELEVANCE OF HEPATITIS B VIRAL MUTATIONS", Hepatology, Vol. 31, No. 5, pages 1037-1044, (2000)	
		COOREMAN et al.; "VACCINE-AND HEPATITIS B IMMUNE GLOBULIN-INDUCED ESCAPE MUTATIONS OF HEPATITIS B VIRUS SURFACE ANTIGEN"; J. Biomed. Sci., Vol. 8, pages 237-247, (2001)	
		PETERSON et al.; "ANTIGENIC STRUCTURE OF HEPATITIS B SURFACE ANTIGEN: IDENTIFICATION OF THE "d" SUBTYPE DETERMINANT BY CHEMICAL MODIFICATION AND USE OF MONOCLONAL ANTIBODIES"; The Journal of Immunology, Vol. 132, No. 2, pages 920-927, (1984)	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

3

Sheet 2 of				
	Sheet	2	of	

Complete if Known			
Application Number	10/561,343		
Filing Date	December 20, 2005		
First Named Inventor	KRUPKA		
Art Unit			
Examiner Name			
Attorney Docket Number	05552.1464		

NON PATENT LITERATURE DOCUMENTS	
JILG; "NOVEL HEPATITIS B VACCINES"; Vaccine, Vol. 16, pages S65-S68, (1998)	
CARMAN et al.; "HEPATITIS B VIRUS ENVELOPE VARIATION AFTER TRANSPLANTATION WITH AND WITHOUT HEPATITIS B IMMUNE GLOBULIN PROPHYLAXIS"; Hepatology, Vol. 24, No. 3, pages 489-493, (1996)	-
MÜLLER et al.; "LIVER TRANSPLANTATION IN HBs ANTIGEN (HBsAg) CARRIERS   PREVENTION OF HEPATITIS B VIRUS (HBV) RECURRENCE BY PASSIVE IMMUNIZATION"; Journal of Hepatology, Vol. 13, pages 90-96, (1991)	
SAMUEL et al.; "LIVER TRANSPLANTATION IN EUROPEAN PATIENTS WITH THE HEPATITIS B SURFACE ANTIGEN"; The New England Journal of Medicine, Vol. 329, No. 25, pages 1842-1847, (1993)	
BRIND et al.; "EVIDENCE FOR SELECTION OF HEPATITIS B MUTANTS AFTER LIVER TRANSPLANTATION THROUGH PERIPHERAL BLOOD MONONUCLEAR CELL INFECTION"; Journal of Hepatology, Vol. 26, pages 228-235, (1997)	
FISHER et al.; "HEPATITIS B VIRUS VARIANTS ASSOCIATED WITH CLINICALLY SEVERE RECURRENCE AFTER LIVER TRANSPLANTATION"; Transplantation Proceedings, Vol. 31, pages 492-493, (1999)	
GHANY et al.; "HEPATITIS B VIRUS S MUTANT IN LIVER TRANSPLANT RECIPIENTS WHO WERE REINFECTED DESPITE HEPATITIS B IMMUNE GLOBULIN PROPHYLAXIS"; Hepatology, Vol. 27, No. 1, pages 213-222, (1998)	*
PROTZER-KNOLLE et al.; "HEPATITIS B VIRUS WITH ANTIGENICALLY ALTERED HEPATITIS B SURFACE ANTIGEN IS SELECTED BY HIGH-DOSE HEPATITIS B IMMUNE GLOBULIN AFTER LIVER TRANSPLANTATION"; Hepatology, Vol. 27, No. 1, pages 254-263, (1998)	
 CARMAN et al.; "GENETIC VARIATION IN HEPATITIS B VIRUS"; Gastroenterology, Vol. 102. No. 2, pages 711-719, (1992)	
CARMAN; "THE CLINICAL SIGNIFICANCE OF SURFACE ANTIGEN VARIANTS OF HEPATITIS B VIRUS"; Journal of Viral Hepatitis, Vol. 4, Suppl. 1, pages 11-20, (1997)	
SWENSON et al.; "DETERMINATION OF HBsAg SUBTYPES IN DIFFERENT HIGH RISK POPULATIONS USING MONOCLONAL ANTIBODIES"; Journal of Virological Methods, Vol. 33, pages 27-38, (1991)	
BLITZ et al.; "ANTIGENIC DIVERSITY OF HEPATITIS B VIRUS STRAINS OF GENOTYPE F IN AMERINDIANS AND OTHER POPULATION GROUPS FROM VENEZUELA"; Journal of Clinical Microbiology, Vol. 36, No. 3, pages 648-651, (1998)	
ASHTON-RICKARDT et al.; "MUTATIONS THAT CHANGE THE IMMUNOLOGICAL SUBTYPE OF HEPATITIS B VIRUS SURFACE ANTIGEN AND DISTINGUISH BETWEEN ANTIGENIC AND IMMUNOGENIC DETERMINATION", Journal of Medical Virology, Vol. 29, pages 204-214, (1989)	
OHBA et al.; "RELATIONSHIPS BETWEEN SEROTYPES AND GENOTYPES OF HEPATITIS B VIRUS: GENETIC CLASSIFICATION OF HBV BY USE OF SURFACE GENES"; Virus Research, Vol. 39, pages 25-34, (1995)	
CARMAN et al.; "FULMINANT REACTIVATION OF HEPATITIS B DUE TO ENVELOPE PROTEIN MUTANT THAT ESCAPED DETECTION BY MONOCLONAL HBsAg ELISA"; The Lancet, Vol. 345, pages 1406-1407, (1995)	_
OKAMOTO et al.; "MUTATIONS WITHIN THE S GENE OF HEPATITIS B VIRUS TRANSMITTED FROM MOTHERS TO BABIES IMMUNIZED WITH HEPATITIS B IMMUNE GLOBULIN AND VACCINE"; Pediatric Research, Vol. 32, No. 3, pages 264-268, (1992)	
ZHANG et al.; "INCREASING HETEROGENEITY OF THE 'a' DETERMINANT OF HBsAg FOUND IN THE PRESUMED LATE PHASE OF CHRONIC HEPATITIS B VIRUS INFECTION"; Scand. J. Infect. Dis. Vol. 28, pages 9-15, (1996)	
ZUCKERMAN et al.; "MUTATIONS IN S REGION OF HEPATITIS B VIRUS"; The Lancet, Vol. 343, pages 737-738, (1994)	
SMITH et al.; "COMPARISON OF BIOSEQUENCES"; Advances in Applied Mathematics, Vol. 2, pages 482-489, (1981)	
SCHWARTZ et al.; "MATRICES FOR DETECTING DISTANT RELATIONSHIPS"; Atlas of Protein Sequence and Structure, pages 353-358, (1978)	
GRIBSKOV et al.; SIGMA FACTORS FROM <i>E.COLI, B. SUBTILIS</i> , PHAGE SP01, AND PHAGE T4 ARE HOMOLOGOUS PROTEINS"; Nucleic Acids Research, Vol. 14, No. 16, pages 6745-6763, (1986)	
SAMBROOK et al.; "MOLECULAR CLONING: A LABORATORY MANUAL, 2 <sup>ND</sup> EDITION"; Cold Spring Harbor Laboratory Press, New York, pages i-xxxviii, (1989)	
AUSUBEL et al.; "A COMPENDIUM OF METHODS FROM CURRENT PROTOCOLS IN MOLECULAR BIOLOGY"; Short Protocols in Molecular Biology, 2 <sup>rd</sup> Edition, John Wiley & Sons, pages iii-xviii, (1992)	
KOEHLER et al.; "CONTINUOUS CULTURES OF FUSED CELLS SECRETING ANTIBODY OF PREDEFINED SPECIFICITY"; Nature, Vol. 256, pages 495-497, (1975)	

DS Form PTO/SB	/08: Substitute for for	m 1449A/PTO		С	omplete if Known	
				Application Number	10/561,343	
INFO	RMATION D	ISCLOSE	JRE	Filing Date	December 20, 2005	
	TEMENT BY			First Named Inventor	10/561,343 December 20, 2005 KRUPKA	
317	I CIVILIA I DI	AFFLIOA	714 1	Art Unit		
	(Use as many sheets	as necessary)		Examiner Name		
Sheet	3	of	3	Attorney Docket Number	05552.1464	

NON PATENT LITERATURE DOCUMENTS	
MIMMS et al.; "DISCRIMINATION OF HEPATITIS B VIRUS (HBV) SUBTYPES USING MONOCLONAL ANTIBODIES TO THE PreS1 AND PreS2 DOMAINS OF THE VIRAL ENVELOPE"; Virology, Vol. 176, Pages 604-619, (1990)	

Examiner	Date	
	Date	
Signature	Considered	
Olgradus	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.